HFE-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
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June 19, 1998

WARNING LETTER NO. 98-NOL-25

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Lawrence T. Dorsey, Administrator/CEO
University Medical Center
2390 West Congress Street
Lafayette, Louisiana 70502

Dear Mr. Dorsey:

During an inspection of University Medical Center, located at 2390 West Congress Street, Lafayette, Louisiana, on May 12-14, 1998, our investigator documented violations of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR), Parts 600-680 as follows:

1. Failure to adequately determine the suitability of persons to serve as the source of whole blood/source plasma [21 CFR 640.3(a) & (b) and 21 CFR 640.63(a), (b), & (c)] in that:
   a) Blood Bank Donor Cards were not fully completed for four of 33 cards reviewed. Temperature and pulse were not recorded for donor [redacted] identification number [redacted] donor [redacted] identification number [redacted], donor [redacted] identification number [redacted] and donor [redacted] identification number [redacted]
   b) Blood Bank Donor Cards for donors [redacted] were not completed at the time of the screening physical examination but after the oversight had been brought to the firm's attention;
   c) The Blood Bank Donor Cards do not document that the donor is asked any medical history questions that identify him as being at increased risk of Creutzfeldt-Jacob Disease (CJD).

2. Failure to maintain and/or follow adequate written standard operating procedures [21 CFR 606.100(b)] in that:
   a) Firm acknowledged receipt of FDA's memo concerning CJD but has failed to incorporate it into their Donor Suitability Questionnaire;
   b) Procedure used to prepare platelets from whole blood units was not performed per firm's written SOP;

c) Donor Screening procedure does not allow employees to determine unexplained changes in weight as per the firm's written "Donor Suitability SOP";
d) Donor Suitability SOP does not contain the actual procedure used to determine donor temperature.

3. Failure to maintain concurrent, detailed and/or accurate records (21 CFR 606.160(a)] in that:
   a) Production records, Blood Bank Donor Cards, Component Preparation Records, and Unit Testing Worksheets are not reviewed and approved by the quality control unit to determine compliance with all established and approved written procedures.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include, but are not limited to seizure, injunction and/or civil penalties.

You should notify this office in writing, within 15 days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to Carolyn S. Olsen, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the Agency staff, you may contact Ms. Olsen at telephone number (504) 589-7166.

Sincerely,

Charles D Scarbrough /for

James E. Gamet
District Director
New Orleans District

Enclosures: FDA-483

/tjt